

Application No.: 10/735,602

Docket No.: JCLA10516

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AUG 23 2006Present Status of the Application

The Office Action rejected claims 1-8, 10-13 and 15 under 35 U.S.C. 102(b), as being anticipated by Bellhouse et al. (WO/94/24263).

Applicant has amended claims 1 and 11 to more clearly define the present invention. The limitation added in claims 1 and 11 is described at paragraph [0009] of the specification, and no new matter is entered. After entry of the foregoing amendments, claims 1-15 remain pending in the present application, and reconsideration of those claims is respectfully requested.

Rejection under 35 U.S.C 102 (b)

*Applicant respectfully traverses the 102(b) rejection of claims 1-8, 10-13 and 15 because Bellhouse et al. (WO/94/24263) does not teach every element recited in these claims.*

In order to properly anticipate Applicants' claimed invention under 35 U.S.C 102, each and every element of claim in issue must be found, "either expressly or inherently described, in a single prior art reference". "The identical invention must be shown in as complete details as is contained in the .... claim. Richardson v. Suzuki Motor Co., 868 F. 2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)." See M.P.E.P. 2131, 8<sup>th</sup> ed., 2001.

The present invention is in general related a method for delivering a biological material using a gene gun and a method for gene transformation by using a gene gun respectively as claims 1 and 10 recite:

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Claim 1. A method for delivering a biological material using a gene gun, comprising:  
providing the gene gun comprising a pressurized chamber, a sprayer, a controller valve and a material delivery system;  
*placing a sample solution into the material delivery system*, wherein the sample solution comprises at least the biological material;  
*triggering the gene gun and providing a gas through the controller valve to the pressurized chamber until the gas establishes a pressure lower than 4 atm*;  
releasing the sample solution from the material delivery system, so that the sample solution is accelerated by the gas in the pressurized chamber; and  
discharging the sample solution out of the sprayer, wherein the sprayer includes a spray nozzle and a spray tube, and the spray nozzle comprises an interior contour, wherein the interior contour of the spray nozzle comprises a diverging part and a converging part and the spray tube is a diverging straight tube, so that a discharge speed of the sample solution is supersonic and the biological material is evenly injected into a target.

Claim 11. A method for gene transformation by using a gene gun, comprising:  
providing the gene gun comprising a pressurized chamber, a sprayer, a controller valve and a material delivery system;  
*placing a sample solution into the material delivery system*, wherein the sample solution comprises at least a nucleic acid;  
*triggering the gene gun and providing a gas through the controller valve to the pressurized chamber to establish a pressure lower than 4 atm*, wherein the gas is a nitrogen gas or a helium gas;  
releasing the sample solution from the material delivery system after the gas in the pressurized chamber establishes the pressure, so that the sample solution is accelerated by the gas in the pressurized chamber; and  
discharging the sample solution out of the sprayer, wherein the sprayer includes a spray nozzle and a spray tube, and the spray nozzle comprises an interior contour, wherein the interior contour of the spray nozzle comprises a diverging part and a converging part and the spray tube is a diverging straight tube, so that a discharge speed of the sample solution is supersonic and the biological material is evenly injected into a target.

Applicant respectfully submits Bellhouse fails to disclose, teach or suggest the sample used in the delivery system is a sample solution, and the pressured chamber is provided with a pressure lower than 4 atm, and therefore Bellhouse does not teach each and every element in claims 1 and 11.

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Bellhouse discloses the delivery system is used for particles delivery in the citation. In particular, Bellhouse teaches, at page 2, lines 17-24, "Drug delivery by liquid jet causes skin damage and bleeding and offers no advance over needles in preventing the spread of blood-borne diseases. Thus, the main advantages which flow from the invention include no needle and less pain; no risk of infection delivery of drugs in natural, solid form; quicker and safer to use than liquid drug, by syringe and needle; and no sharps to dispose of". Bellhouse also teaches, at page 12, lines 29-32, "a particular advantage of the new technique of injecting dry powdered drugs is that it can be used for delivering a stable mixture of drugs, which are unstable when mixed wet". That is, the delivery system of the citation is not suitable for sample solution delivery. However, in claims 1 and 11 of the present application, a sample solution is delivered by using the gene gun, and thus micro-carriers (gold particles or tungsten particles) are not needed.

In addition, Bellhouse teaches, at page 7, lines 16-17, "burst pressures of 42, 61 and 100 atmospheres produced penetration depths of 38, 50 and 70 units respectively". In other words, the pressure established in the delivery system of the citation is much higher than 4 atm. However, in claims 1 and 11 of the present application, the pressured chamber is provided with a pressure lower than 4 atm. The present invention only needs to establish the pressure lower than 4 atm in the gene gun to accelerate the sample solution for delivering the sample.

For at least the foregoing reasons, Applicant respectfully submits that independent claims 1 and 11 patently define over the prior art references, and should be allowed. For at least the same reasons, dependent claims 2-10 and 12-15 patently define over the prior art as a matter of

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law, for at least the reason that these dependent claims contain all features of their respective independent claim.

In particular, regarding to claims 7 and 12, the limitation thereof is the sample solution is accelerated to a speed of 200-300 m/s by the gas. The present invention just needs to establish the pressure lower than 4 atm in the gene gun, and then the sample solution can be accelerated to a high speed of 200-300 m/s. However, the citation needs the pressure much higher than 4 atm in the delivery system to accelerate the particle sample so as to have a particle velocity between 200-2500 m/sec (page 7, line 13). Therefore, the method of the citation is different from the present application.

Regarding to claims 9 and 14, the office action stated the angle between the diverging part and the center axis of the spray tube of the citation is also less than 15 degrees in Fig. 1. However, applicant respectfully disagrees. As a matter of fact, the citation does not clearly disclose the angle value between the diverging part and the center axis of the spray tube, and the conjecture from the drawing is not proper because the drawing is just a diagram but not a real structural drawing. In addition, the limitation in claims 9 and 14 also comprises “  $rt < Rt < 2rt$ , wherein  $Rt$  represents a curvature radius of the converging part,  $rt$  is a radius of the spray neck”. The citation does not teach the limitation.

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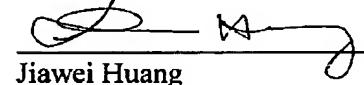
**CONCLUSION**

For at least the foregoing reasons, it is believed that the pending claims are in proper condition for allowance. If the Examiner believes that a telephone conference would expedite the examination of the above-identified patent application, the Examiner is invited to call the undersigned.

Respectfully submitted,  
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